



# Product Specification

Product group : MCC  
 Brand name : Pharmacel®112  
 Article code : SAP 743842; Navision 13115-5355  
 Product description: Microcrystalline Cellulose  
 Document No. : PD-0601 Page 1 of 2

**Manufacturer** : DFE Pharma India Private Limited, India

**Production site** : DFE Pharma India Private Limited, Cuddalore, India

**Product name** : Pharmacel® 112  
 Conforms to USP-NF, Ph. Eur., JP and IP Specifications on date of manufacture

**Product description** : A white or almost white, fine, crystalline or granular, slightly hygroscopic powder having fluidity and odorless

**Solubility** : Practically insoluble in water, acetone, anhydrous ethanol, toluene, diethyl ether, dilute acids and in a 50 g/L solution of Sodium hydroxide

## Physical-Chemical data

## Specification

Identification A (USP, Ph.Eur.), 2 (JP)	Pass
Identification B (USP, Ph.Eur.), 1 (JP)	Pass
Identification C (USP, Ph.Eur.), 3 (JP)	Max. 350
Identification C (IP)	Pass
Solubility in ammoniacal copper tetrammine	Pass
pH	5.5 - 7.0
Conductivity	Max. 75 µS/cm
Ether soluble substances	Max. 0.05 %
Water soluble substances	Max. 0.20 %
Heavy metals	Max. 10 ppm
Assay (IP)	97.0 - 102.0 %
Arsenic	Max. 2 ppm
Starch and Dextrins (IP)	Pass
Organic impurities (IP)	Pass
Loss on Drying	Max. 1.5 %
Residue on ignition	Max. 0.05 %
Bulk density	0.28 - 0.34g/mL



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### Microbiological data

Total Aerobic Microbial Count  
Total Yeast and Mould Count  
*Escherichia coli* in 10g  
*Pseudomonas aeruginosa* in 10g  
*Staphylococcus aureus* in 10g  
*Salmonella* species in 10g  
*Shigella* species in 10g

### Specification

Max. 100CFU/g  
Max. 20CFU/g  
Negative  
Negative  
Negative  
Negative  
Negative

### Particle Size Distribution (Airjet, Malvern)

Particle size % < 32µm  
Particle size % < 75µm  
Particle size % < 250µm  
Particle size D10  
Particle size D50  
Particle size D90

### Specification

Max. 30.0%  
30.0 - 55.0 %  
Min. 92.0 %  
20 - 50 µm  
80 - 130 µm  
160 - 240 µm

**Packaging** : A white multi-layered polyethylene-aluminum bag with a polyethylene inner liner, 25Kg net.

**Storage** : Keep in original, unopened packing in ambient conditions, protected from humidity and away from strongly odorous materials. The storage of Pharmacel® 112 in original special packaging ensures complete protection from moisture absorption. If the packaging is opened, we strongly recommend closing the bag by heat-sealing, when material is not fully used.

**Shelf life** : For storage periods exceeding 48 months, we recommend re-testing.

This document substitutes all previous versions issued for the brand names mentioned above.  
We trust this information, which is made up to the best of our knowledge, will be helpful to you.

**Name** : Dr. Bastiaan Dickhoff  
**Job title** : Director Innovation & Technical Solutions

**Signature** :

A blue ink facsimile signature of B. Dickhoff, written in a cursive style.

This document is controlled by a validated, electronic system and is valid without signature.  
The above facsimile signature is only for display.